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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 09/719,316            | 12/11/2000  | Yasuhiro Shimizu     | 55475(968)          | 7005             |
| 21874                 | 7590        | 09/08/2005           | EXAMINER            |                  |
| EDWARDS & ANGELL, LLP |             |                      | BOYD, JENNIFER A    |                  |
| P.O. BOX 55874        |             |                      | ART UNIT            | PAPER NUMBER     |
| BOSTON, MA 02205      |             |                      | 1771                |                  |

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                  |                   |
|------------------------------|------------------|-------------------|
| <b>Office Action Summary</b> | Application No.  | Applicant(s)      |
|                              | 09/719,316       | SHIMIZU, YASUHIKO |
|                              | Examiner         | Art Unit          |
|                              | Jennifer A. Boyd | 1771              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 13 June 2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1 – 3, 5, 8 – 10 and 11 – 28 is/are pending in the application.
- 4a) Of the above claim(s) 11-28 is/are withdrawn from consideration.
- 5) Claim(s) 1 - 3,9 is/are allowed.
- 6) Claim(s) 5,8 and 10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The Applicant's Amendments and Accompanying Remarks, filed June 13, 2005, have been entered and have been carefully considered. Claims 1 and 5 are amended, claims 11 – 28 are withdrawn and claims 1 – 3, 5, 8 – 10 and 11 – 28 are pending. In view of Applicant's amendment to claim 1, the Examiner withdraws the 35 USC 112, 2<sup>nd</sup> paragraph rejection as detailed in the Office Action dated March 11, 2003. The invention as currently claimed is unpatentable for reasons herein below.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102/103***

3. Claim 5 remains rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bell (US 6,179,872). The details of the rejection can be found in the Office Action dated March 11, 2003. The rejection is maintained.

Claim 5 has been amended to include the limitation that the collagen is formed by performing a freezing, freeze-drying *and thermal dehydration crosslinking procedure*. Bell teaches that the strength of the matt may be increased by standard collagen crosslinking methods such as ultraviolet, dehydrothermal or chemical crosslinkers (column 13, lines 5 – 20).

It should be noted even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same or an obvious variant from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the Applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

***Claim Rejections - 35 USC § 103***

4. Claims 8 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (US 6,179,872) in view of Yasuhiko (WO 98/22157). The details of the rejection can be found in paragraph 7 of the previous Office Action dated October 15, 2003. The rejection is maintained.

***Allowable Subject Matter***

5. Claims 1 – 3 and 9 are allowed. The reasons for allowance have been set forth in paragraph 8 of the Office Action dated October 15, 2003.

***Response to Arguments***

6. Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive.

Applicant argues that Bell does not teach or suggest the collagen material as recited in claim 5. Applicant argues that claim 5 as amended requires a thermal dehydration which provides a further advantage to the present invention in that no chemical crosslinker is used. The

Examiner submits that Bell does teach that the strength of the matt may be increased by standard collagen crosslinking methods such as ultraviolet, dehydrothermal or chemical crosslinkers (column 13, lines 5 – 20). The Examiner submits that the dehydrothermal crosslinker would be equivalent to Applicant’s “thermal dehydration crosslinking”. If Applicant submits that the thermal dehydration crosslinking procedure is different than Bell’s “dehydrothermal crosslinker” and would result in materially different final products, the Applicant must submit evidence rather than arguing that the final products differ.

### *Conclusion*

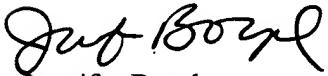
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Boyd  
September 1, 2005



**Ula C. Ruddock**  
Primary Examiner  
Tech Center 1700